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BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,080	UNGER ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006 and 03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *105-120* is/are pending in the application.

4a) Of the above claim(s) *106,107,110-112 and 116-118* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *105,108,109,113-115,119 and 120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Papers filed 27 July 2006 and 3 January 2007 in response to the Final Office Action mailed 3 May 2006 and the Advisory Action mailed 15 August 2006. Claims 106 and 107 were withdrawn from consideration and claims 105 and 108-120 were considered in the 3 May Office Action. Claims 105, 117, 119 and 120 were amended in the 27 July Paper. Claims 105-120 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 July 2006 has been entered.

Election/Restrictions

In the Paper filed 8 February 2006, Applicant elected the species 2-chloro-1,1,1,4,4,4-hexachloro-2-butene as the species for initial prosecution and stated that claims 107, 110 and 116 read on the elected species. However, upon reviewing the claims it was discovered that the elected species is not included among those set forth in the claims. Therefore, claims 107, 110-112 and 116-118 are hereby withdrawn from consideration as directed to a non-elected species. Claim 106 was also withdrawn from consideration in the 3 May Office Action.

Applicant timely traversed the restriction (election) requirement in the 27 October reply and the restriction requirement was made FINAL in the 3 May Office Action.

Claims 105, 108, 109, 113-115, 119 and 120 are presently under consideration.

Response to Amendment and Arguments

Claim Objections

Objection to claim 117 is withdrawn in view of the amendment thereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119 and 120 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As stated in the previous Office Action, none of the teachings found in the specification would suggest 500 milliwatts/cm^2 as an upper limit for a range of energy to be used in the method. Thus, the method of claims 19 and 20 wherein the application of ultrasound is limited to the range of 200-500 milliwatts/cm^2 constitutes impermissible new matter.

In the response to the rejection of record filed 27 July 2006, Applicant contends that the claimed range is supported because the upper limit of 500 milliwatts per cm^2 recited in claim 119 falls within the range of from about 200 milliwatts per cm^2 to about 10 watts per cm^2 contemplated in the disclosure and, therefore, the range recited in claim 119 is completely within the range recited in the original specification.

This argument has been fully considered but is not deemed persuasive. The courts have determined that a subgeneric range is not necessarily supported by the disclosure of a generic range and a species within the subgeneric range. See, e.g., *In re Lukach*, 442 F.2d967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). Each case must be decided on its own facts in terms of what is reasonably communicated to those skilled in the art. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

In the instant case, as pointed out in the previous Office Action, the disclosure as filed does not contemplate a range bounded by an upper limit of 500 milliwatts per cm^2 and there is nothing in the disclosure that would lead one to a range having an upper limit of 500 milliwatts per cm^2.

Applicant is reminded that, According to MPEP §2163, "To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation

in a claim 'is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.'" (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998); emphasis added).

For the reasons of record, the skilled artisan at the time the patent application was filed would not have understood that the description requires the range recited in the instant claim 119. Therefore, the range constitutes impermissible new matter.

Claims 105, 108, 109, 113-115, 119 and 120 **stand rejected** under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for delivering a nucleic acid into a cell comprising administering a composition comprising a nucleic acid and an organic halide, wherein the composition further comprises a lipid carrier or wherein ultrasound is applied to said cell, does not reasonably provide enablement for the broad scope of a method of delivering any compound into a cell by administration of said compound with any organic halide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In response to the *prima facie* rejection and arguments of record, Applicant first contends that the claims have been narrowed by the recitation of "therapeutically beneficial compound" to a more reasonable breadth. However, as clearly evidenced by the Markush group of claim 105, the "therapeutically beneficial compound" of the claims embraces a tremendously diverse genus of structurally and functionally distinct molecules. Therefore, the amendment does not narrow

the scope of the claims such that the skilled artisan would be able to practice the full scope of the claimed method without undue experimentation.

Applicant next points out that it is well known in the art that the delivery of many materials to a cell is often very difficult, particularly if the compound has low aqueous solubility, and one solution to this problem is improve delivery by the application of ultrasound. Applicant contends that combining a compound with a halide and applying ultrasound leads to improved transfection and once this technique is taught with respect to a nucleic acid sequence those skilled in the art would understand that the same general methodology can be easily utilized with respect to other compounds. (P. 13, ¶2.) Applicant contends that because the Examiner concedes that the method is enabled when the compound is a nucleic acid the entire scope of the claims must be enabled. (Bridging pp. 13-14.)

Applicant further contends that because the specification teaches how to practice the method for a nucleic acid, including steps such as mixing the nucleic acid with a halide and applying ultrasound, the specification teaches every relevant detail of the process. Applicant asserts that all that is required to practice the invention with other compounds would be to adjust ratios of the compounds.

Applicant contends that *In re Fisher* requires only reasonable correlation between the disclosure and the scope of the claims, not absolute correlation.

These arguments have been fully considered but are not deemed persuasive. It is acknowledged that *Fisher* requires only reasonable correlation; however, for the reasons set forth in the previous Office Action, the scope actually enabled by the disclosure does not reasonably correlate with the scope of protection sought. Although it is acknowledged that the disclosure is

enabling for delivering a nucleic acid into a cell, it must be made clear that, in terms of their chemical properties, all nucleic acids are essentially the same. That is, all nucleic acids are comprised of the same four nucleoside bases arranged in different order, wherein the sequence of the bases does not materially alter the chemical properties of the compound.

In contrast, genus of molecules such as proteins is made up of species having highly divergent chemical properties, which properties are much different from the chemical properties of the nucleic acids reduced to practice. As pointed out in the previous Office Action (p. 14), the "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability.

The Examiner's position is substantiated by a number of factors evidencing unpredictability in extending the teachings of the specification beyond what is demonstrated in the working examples including the art recognized difficulties encountered in delivering one large class of molecules (i.e., proteins) across plasma membranes (see, e.g., the discussion bridging pp. 7-8 of the previous Office Action); the art recognized unpredictability of structural modifications on delivery molecule function (see, e.g., the discussion of Godbey et al. bridging pp. 7-8 of the Office Action mailed 24 August 2004); the absence of any teaching in the art demonstrating delivery of any compound across a cell wall as contemplated on page 14 of the

specification; and the nascent state of the art with regard to microbubble enhanced drug uptake (see, e.g., the discussion bridging pp. 8-9 of the previous Office Action).

Given the nascent state of the relevant art and the tremendous breadth of the claims, the skilled artisan seeking to practice the instant claimed method according to its full scope would be forced to identify which of the many thousands of combinations of organic halide and compound encompassed by the claims would be operative in a method of introducing a compound into a cell and determine how to apply ultrasound sufficient to induce uptake of any compound into any cell such that a useful outcome is obtained. By way of guidance in determining the operative embodiments of the invention, the specification provides only suggestions of preferred embodiments of the organic halide and very limited working examples, which provide the method practiced with a single compound (*i.e.*, DNA) and five species of organic halide, wherein the composition further comprises additional ingredients (*i.e.*, transfection reagents) that would provide delivery of a nucleic acid into a cell even in the absence of the organic halide. Given these teachings the skilled artisan would have no idea which embodiments of the claimed invention would be operative, beyond those wherein the compound is a nucleic acid and the method further comprises a lipid carrier or application of ultrasound. Thus, operability of each of the many thousands of combinations encompassed by the claims would have to be determined independently by empirical experimentation.

Contrary to Applicant's assertion, a teaching that the compound to be delivered should be mixed with a halide does not enable the broad scope of what is claimed. Rather, what is required is a teaching of which compound mixed with which organic halide provides a composition capable of delivery into any cell, including which organic halides can be used in conjunction

with ultrasound to deliver a compound across a cell wall. Applicant's contention that practicing the invention with respect to compounds other than nucleic acids would require only adjustments with respect to the ratios of the compounds and with respect to the protocol of applying ultrasound is simply not consistent with the broad scope of the claims, the chemically heterogeneous nature of compounds to be delivered and the unpredictable nature of the art.

Finally, Applicant cites *In re Wands* and contends that a reasonable quantity of experimentation is allowed if it is routine or if the specification provides enough guidance. However, with regard to the legal standard for "undue experimentation", *In re Wands* is clear, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* ...They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims" (8 USPQ2d 1400, page 1404). The present arguments appear to be Applicant's opinion of what is routine experimentation and not the legal analysis set forth in *In re Wands*. In contrast, analysis of the instant claims according to the "Forman factors" is clearly set forth in the previous Office Actions.

It is further noted that the facts in *Wands*, particularly the scope of what is claimed and the level of predictability in the art, are quite different from the facts in the instant case. The claims in *Wands* were limited to a product consisting of a single class of antibody capable of detecting a single antigen, as opposed to the broad scope of the method presently claimed, and the Court in *Wands* reasoned as follows (1406-1407; emphasis added):

> When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *Ex parte Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known. The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.

In contrast to the facts in Wands, the instant claims are tremendously broad, delivering chemically disparate compounds into cells is not routine and the working examples are far from representative of the vast majority of embodiments within the scope of the claims.

Thus, in view of the record as a whole, it is clear that practicing the invention commensurate with the full scope of what is claimed would require undue experimentation. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 119 and 120 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Unger (WO 94/28780; made of record in the previous Office Action).

In response to the *prima facie* rejection of record, Applicant contends that Unger does not render obvious the claimed invention because Unger provides no motivation or suggestion to the energy flux of 200-500 mW per cm^2. Applicant contends that the Examiner has provided no justification why one skilled in the art will be motivated to modify Unger to arrive at what is claimed. Applicant contends that a showing that the proposed modification is desirable is required.

These arguments have been fully considered but are not deemed persuasive. As described in the previous Office Action, the instant application teaches that the range recited in the claim falls within a range typical of therapeutic ultrasound (p. 49, ¶2). Unger *et al.* teaches, "Higher

energy ultrasound such as commonly employed in therapeutic ultrasound equipment is preferred for activation of the therapeutic containing gaseous precursor-filled liposomes" (p. 56, ll. 16-19; emphasis added). Thus Unger et al. also provides a generic teaching that the ultrasound energy in the range commonly employed in therapeutic applications is desirable for use in the method. Therefore, the only distinction between what is claimed and what is taught in the prior art is the recitation in the claim of what appears to be an optimum range, which difference does not support patentability of subject matter claimed.

Contrary to Applicant's characterization, the Examiner does provide substantial legal basis for concluding that a claim that differs from the prior art only insofar as it recites a range falling within a generic teaching found in the art is *prima facie* obvious. The Examiner cites, *inter alia*, *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), which states, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" and *In re Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

Thus, contrary to Applicant's assertions, the Examiner has not resorted to speculation, unfounded assumptions or hindsight reconstruction. Instead, the *prima facie* rejection provides a reasoned analysis based upon the facts in the instant case and relevant legal precedent.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §103(a) as obvious over the art.

New Grounds

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 105 and 113 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Reinhardt *et al.* US Patent No. 5,425,366.

Reinhardt *et al.* teaches the production of microparticles consisting of a synthetic biodegradable polymer and a gas (i.e., contrast agents; see especially col. 5, ll. 31-50), wherein the preferred gasses include various organic halides (see col. 5, ll. 59-68). Reinhardt *et al.* further teaches a method wherein the microparticles are delivered into a patient and administration of ultrasound at an energy level sufficient to induce bursting of the microparticles (see especially col. 3, l. 43 through col. 5. l. 13). Thus, the method of Reinhardt *et al.* comprises administering a microparticle composition comprising a compound (*i.e.*, a synthetic biodegradable polymer) and an organic halide, wherein the composition does not comprise a liposome, and applying ultrasound at an energy level sufficient to burst the microparticle according to the instant claim 105, wherein the composition comprises a contrast agent according to claim 113. Although, given the unpredictable nature of the art, it is not clear to what degree a compound would be

delivered into a cell by the method of Reinhardt, it is reasonable to expect that some small amount of the constituents of the microparticles would enter one or more cells in the vicinity of the bursting microparticles. As the instant claims do not require any particular degree of uptake of the therapeutically beneficial compound, the method of Reinhardt et al., absent evidence to the contrary, is deemed to anticipate the claims of the instant application.

It is noted that this rejection should not be construed as an admission that the claims are broadly enabled for a method of delivering any compound into a cell by administering any composition comprising the compound and an organic halide and applying ultrasound. First, the teachings of the prior art also fail to enable the broad scope of what is presently claimed. Furthermore, enablement under 35 U.S.C.§112, first paragraph, requires that the disclosure teach how to make and use the claimed invention. Therefore, to be enabling, the disclosure must teach the skilled artisan how to practice the claimed method of delivering a compound into a cell such that a useful degree of uptake is obtained. In contrast, anticipation under 35 USC §102 does not require a patentably useful outcome.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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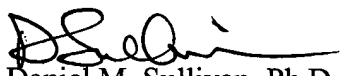

Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636